

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent No.:	7,488,822	Conf. No.:	5696
Issued:	February 10, 2009	TC/A.U.:	1464
Appl. No.:	10/767,813	Examiner:	Wang, Shengjun
Filed:	January 29, 2004		
Patentee:	Zhang et al		
Cust. No.:	38199		
Title:	CYCLOCARBAMATE DERIVATIVES AS PROGESTERONE RECEPTOR MODULATORS		

Mail Stop Patent Extension  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sirs:

**STATEMENT OF FACTS  
ACCOMPANYING REQUEST FOR RECONSIDERATION OF PATENT TERM  
ADJUSTMENT PURSUANT TO 37 C.F.R. § 1.705(d)**

1. This Statement of Facts is respectfully submitted in support of the Application for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. § 1.705(d) for the above-referenced patent. For the reasons set forth below, it is respectfully request that Patentees be granted a patent term adjustment of 1414 days.

2. Erroneous Calculation of Delay

The US Patent and Trademark Office failed to take into account all of the patent term adjustment (PTA) days that Patentees are entitled to pursuant to 35 C.F.R. § 154(b)(1)(B) ("B Delay") when calculating the patent term adjustment. The PTA under 35 U.S.C. § 154(b) indicated on the above-identified patent is 859 days (a copy of the face of the patent is submitted herewith as Exhibit "A"). This determination of 859 days is in error as it only reflects a portion of the days to which Patentees are entitled.

3. Examination Delays Pursuant to 37 C.F.R. §1.702 and §1.703

Pursuant to 35 U.S.C. §154(b), the term of patent shall be extended one day for each day that the Office failed to take certain action within the time frame specified in 35 U.S.C. § 154(b)(1)(A) [37 C.F.R. §1.702(a)] (hereinafter “A Delay”) and failed to issue a patent within three years of the actual filing date of the above-referenced application in accordance with 35 U.S.C. § 154(b)(1)(B) [37 C.F.R. §1.702(b)] (hereinafter “B Delay”). In the above-referenced patent, Patentees are entitled to a period of examination delay equal to the sum of the periods of delay under 37 C.F.R. §1.703(a) and (b) for the following reasons.

(A) “A Delay”

Pursuant to 37 C.F.R. §1.703(a)(1), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 14 months after the actual filing date of the application (hereinafter “14 Month Delay”). Thus, under 37 C.F.R. §1.703(a)(1) Patentees are entitled to a PTA equal to the period between the date which is 14 months from the filing date and the date of mailing of a first Office Action under 35 U.S.C. §132 (*i.e.*, from March 30, 2005 to July 2, 2007 or 825 days).

In addition, pursuant to 37 C.F.R. §1.703(a)(2), Patentees are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. §132 not later than 4 months after the date of reply under 37 C.F.R. §1.111 (hereinafter “4 Month Delay”). Thus, under 37 C.F.R. §1.703(a)(2), Patentees are entitled to a PTA equal to the period between the date which is 4 months from Patentees’ reply and the date of a mailing of an action under 35 U.S.C. §132 (*i.e.*, from August 3, 2008 to September 5, 2008 or 34 days).

The total of 859 days reflected in on the face of the above-identified patent reflects the number of days attributable to delay under 37 C.F.R. §1.703(a)(1) and (2).

(B) “B Delay”

35 U.S.C. §154(b) and 37 C.F.R. §1.702(b) require issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. §111(a), *i.e.*, by January 30, 2007. Pursuant to 37 C.F.R. §1.702(b)(1-5), the B Delay

period shall not include certain periods specifically enumerated in the rule, none of which are applicable here. Thus, the B Delay period runs from the day after the date that is 3 years from the actual filing date of the application (January 30, 2007) until the day the patent is granted (February 10, 2009), to provide 743 days<sup>1</sup>.

(C) Total Examination Delay Pursuant to 37 C.F.R. §1.703(f)

As set forth in 37 C.F.R. §1.703(f), the period of examination delay based on the grounds set forth in 37 C.F.R. §1.702 is the sum of the period of A Delay (859 days) and the B Delay (743 days), to provide a total of 1602 days, *to the extent these periods of delay are not overlapping*.

Pursuant to *Wyeth v. Dudas*<sup>2</sup>, A Delay days and B Delay days overlap only when they fall on the same calendar day. In the instant case, the period of 14 Month Delay ended on July 2, 2007. The period of B Delay began on January 30, 2007. Thus, A Delay and B Delay overlap for the period of January 30, 2007 to July 2, 2007, *i.e.* for 154 days. In addition, the entire 4 Month Delay falls on the same calendar days as some of the B Delay period, *i.e.*, for 34 additional days. Therefore, the total period of PTA delay should be reduced by the period of overlap, *i.e.*, 154 days + 34 days = 188 days.

Thus, Patentees are entitled to A Delay + B Delay (to the extent they are not overlapping) = 859 days + 743 days – 188 days = 1414 days of patent term adjustment.

(D) Calculation of Correct Patent Term Adjustment Pursuant to 37 C.F.R. §1.703(f)

As set forth in 37 C.F.R. §1.703(f), Patentees are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay, which is 0 days. Therefore, Patentees submit that the correct patent term adjustment for the above-referenced patent is 1414 days.

---

<sup>1</sup> Note that only the days of B delay that do not overlap with A delay days are included in the final PTA calculation. This is further described in section C, below.

<sup>2</sup> *Civil Action No. 07-1492; 200 US Dist 76063 [D.D.C. September 30, 2008]*.

4. This patent is subject to a terminal disclaimer. 37 C.F.R. §1.705(b)(2)(iii).

5. There were no circumstances during the prosecution of the application resulting in the patent that may be considered to constitute a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. §1.704.

6. In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of **1414 days** of the patent for the above-referenced application.

Dated: 4/8/2009

Respectfully submitted,  
Howson & Howson LLP

By: 

Tracy U. Palovich, PhD  
Registration No. 47,840  
501 Office Center Drive  
Suite 210  
Ft. Washington, PA 19034  
215-540-9200  
215-540-5818(Fax)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent No.:	7,488,822	Conf. No.:	5696
Issued:	February 10, 2009	TC/A.U.:	1624
Appl. No.:	10/767,813	Examiner:	Wang, Shengjun
Filed:	January 29, 2004		
Patentee:	Zhang et al		
Cust. No.:	38199		
Title:	CYCLOCARBAMATE DERIVATIVES AS PROGESTERONE RECEPTOR MODULATORS		

Mail Stop Patent Extension  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sirs:

**APPLICATION FOR PATENT TERM ADJUSTMENT, INCLUDING REQUEST  
FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT  
UNDER 37 C.F.R. §1.705(d)**

Dear Sir:

1. This is a request for reconsideration of the patent term adjustment under 35 U.S.C. §154(b) of 859 days indicated on the above-identified issued patent. It is respectfully requested that Patentees be granted a patent term adjustment of 1414 days.
2. The above-identified patent issued on February 10, 2009. Accordingly, as required by 37 C.F.R. §1.705(d), the instant request is timely filed within two (2) months of issue date of the above-identified patent.
3. Patentees submit herewith a "Statement Under 37 C.F.R. §1.705(b)(2)".

US Patent No. 7,488,822  
Application under 37 C.F.R. 1.705(d)  
April 8, 2009

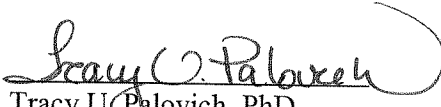
4. In accordance with 37 C.F.R. §1.705(b)(1), please charge the fee set forth in 37 C.F.R. §1.18(e) (\$200.00) to Deposit Order Account No. 08-3040. Please charge any necessary additional fees or credit any overpayments to our Deposit Order Account No. 08-3040.

5. Because this Application for Patent Term Adjustment is being filed to correct an alleged USPTO error, Patentees respectfully request that the Application fee be refunded if this Application for Patent Term Adjustment is decided in Patentees' favor.

Dated: 4/8/2009

Respectfully submitted,  
Howson & Howson LLP

By:

  
Tracy U. Palovich, PhD  
Registration No. 47,840  
501 Office Center Drive  
Suite 210  
Ft. Washington, PA 19034  
215-540-9200  
215-540-5818(Fax)



US00748822B2

(12) **United States Patent**  
**Zhang et al.**(10) **Patent No.:** **US 7,488,822 B2**  
(45) **Date of Patent:** **\*Feb. 10, 2009**(54) **CYCLOCARBAMATE DERIVATIVES AS  
PROGESTERONE RECEPTOR  
MODULATORS**(75) Inventors: **Puwen Zhang**, Audubon, PA (US);  
**Eugene A. Terefenko**, Quakertown, PA  
(US); **Andrew Fensome**, Wayne, PA  
(US); **Jay E. Wrobel**, Lawrenceville, NJ  
(US); **Horace Fletcher, III**, Pottstown,  
PA (US); **Lin Zhi**, San Diego, CA (US);  
**Todd K. Jones**, Solana Beach, CA (US);  
**James P. Edwards**, San Diego, CA  
(US); **Christopher M. Tegley**, Thousand  
Oaks, CA (US)(73) Assignee: **Wyeth**, Madison, NJ (US)(\*) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 859 days.This patent is subject to a terminal dis-  
claimer.(21) Appl. No.: **10/767,813**(22) Filed: **Jan. 29, 2004**(65) **Prior Publication Data**

US 2004/0186101 A1 Sep. 23, 2004

**Related U.S. Application Data**(60) Continuation of application No. 10/386,799, filed on  
Mar. 12, 2003, now Pat. No. 6,713,478, which is a  
division of application No. 09/948,309, filed on Sep. 6,  
2001, now Pat. No. 6,566,358, which is a division of  
application No. 09/552,633, filed on Apr. 19, 2000,  
now Pat. No. 6,509,334.(60) Provisional application No. 60/183,012, filed on May  
4, 1999.(51) **Int. Cl.**  
**C07D 265/12** (2006.01)(52) **U.S. Cl.** ..... **544/92**(58) **Field of Classification Search** ..... 514/183;  
544/92

See application file for complete search history.

(56) **References Cited****U.S. PATENT DOCUMENTS**3,526,621 A 9/1970 Bernardi  
3,635,941 A 1/1972 Weaver  
3,635,964 A 1/1972 Skorcz  
3,917,592 A 11/1975 Kobzina  
4,093,730 A 6/1978 Butti  
4,440,785 A 4/1984 Walsh  
4,518,597 A 5/1985 Narr  
4,617,302 A 10/1986 Robertson  
4,666,913 A 5/1987 Kuhla  
4,670,566 A 6/1987 Walsh  
4,721,721 A 1/1988 Kuhla  
4,792,561 A 12/1988 Walker  
4,822,794 A 4/1989 Spada4,831,027 A 5/1989 Narr  
4,853,473 A 8/1989 Fischer  
4,933,336 A 6/1990 Martin  
5,007,952 A 4/1991 Kume  
5,171,851 A 12/1992 Kim  
5,182,282 A 1/1993 Clemence  
5,246,989 A 9/1993 Iwamoto  
5,300,655 A 4/1994 Ehrgott  
5,414,088 A 5/1995 von der Saal  
5,447,928 A 9/1995 Williams  
5,453,516 A 9/1995 Fischer  
5,475,020 A 12/1995 Johnson  
5,519,021 A 5/1996 Young  
5,521,166 A 5/1996 Grubb  
5,552,412 A 9/1996 Cameron  
5,565,483 A 10/1996 Hewawasam  
5,576,330 A 11/1996 Buzzetti  
5,659,046 A 8/1997 Kameswaran  
5,681,817 A 10/1997 Hodgen  
5,688,808 A 11/1997 Jones  
5,688,810 A 11/1997 Jones  
5,693,646 A 12/1997 Jones

(Continued)

**FOREIGN PATENT DOCUMENTS**

DE 3633861 4/1988

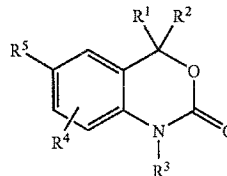
(Continued)

**OTHER PUBLICATIONS**Andreani et al., "Potential antitumor agents XVII(1). Cytotoxic  
agents from indole derivatives and their intermediates", *Acta. Pharm.*  
*Nord.* 1990 2(6):407-414.

(Continued)

*Primary Examiner*—Shengjun Wang*Assistant Examiner*—Timothy E Betton(74) *Attorney, Agent, or Firm*—Paul Carango; Howson &  
Howson LLP(57) **ABSTRACT**

This invention provides compounds of Formula (I):

wherein R<sup>1</sup> and R<sup>2</sup> are independent substituents or are fused  
to form spirocyclic rings; R<sup>3</sup>, R<sup>C</sup>, and R<sup>4</sup> are as defined herein;  
and R<sup>5</sup> is a substituted benzene ring or a substituted five or six  
membered heterocyclic ring having in its backbone 1, 2, or 3  
heteroatoms including O, S, SO, SO<sub>2</sub> or NR<sup>6</sup>; or pharmaceu-  
tically acceptable salt thereof, as well as pharmaceutical com-  
positions and methods using the compounds as antagonists of  
the progesterone receptor.**2 Claims, No Drawings**